

Agenda
CRU April 26, 2016 Meeting Agenda
12:00 PM

Attendance: Dr. Daniel Barboriak, Dr. Mustafa R Bashir, Dr. Bastiaan Driehuys, Dr. Joseph Lo, Dr. James MacFall, Jennifer Korzekwinski, Steven Shipes, Dr. Christopher Vallanat, Gemini Janas, Brittany Price, Tracy Kerby, Dana Sanders, Daniele Marin MD, Dr. Jim Voyvodic, Dr. Kingshuk Choudhury, Samantha Womack

I. Introduction

- Introduction of our newest CRC Brittany Price
Brittany Price was introduced to all those in attendance.
- Approval of March 22, 2016 minutes
Motion to approve by Dr. Driehuys and seconded by Dr. James MacFall. Everyone present voted and approved.
- Activity Summary – 232 Total Studies 42 full committee; 164 expedited; 26 exempt
- 149 Subjects enrolled for 2016,(6 NIH, 2 Federal, 127 Industry, 14 Internal)
- 399 Research Associated Scans performed throughout health system in March 2016
- Patient safety update -
Pro00043649 SAE1 does not represent an UPIRTSO (thumb drive leaving Duke)
Pro00059984 SAE1 does not represent an UPIRTSO (Consented 4 subjects with old consent)
Pro00061284 SAE001 does not represent an UPIRTSO (1-Privacy Notice given to 4 subjects 2-second identifier not on consent 3-Consent with improper watermark signed 4- No documentation of consent Pro00038169 SAE011 in review. (Out of range value noted as out of range, initially declared NCS)
Safety events were discussed. Info will be used as areas to look for during audits.

II. Review of Approved projects (no seed fund requests or issues)

- Pro00072228 Imaging Criteria for Transplant Renal Artery Stenosis
Principal Investigator: Mustafa Bashir
- Pro00069440 Clinical impact of SPECT/CT Tc-99m methylene diphosphonate bone scanning versus MRI in foot and ankle pathology
Principal Investigator: Brandon Howard
- Pro00071819 Imaging Pancreas Transplants
Principal Investigator: Mustafa Bashir
Retrospective studies were discussed and approved.

III. Prospective Studies

- Dr. Peter Kranz, Pro00071254 Epidural patching outcome assessment.—approved out of CRU by Dr. Barboriak after questions answered and changes made by study team.
Details worked out and study has IRB approval and has started enrolling.

- Pro00070445 Focal Breast Pain: Does a normal ultrasound provide reassurance?
Principal Investigator: Karen Johnson
Study is a deception study measuring reassurance and anxiety. The study has minimal financial risk.
The Radiology CRU committee voted to send the study back to the study team with questions. The questions had mainly to do with the consent process, specific hypotheses, the figure of merit, and feasibility of recruitment. Approval is pending all of these questions being answered.
- Pro00063806 Diagnostic Utility of MRI in Female Patients with Nipple Discharge: Prospective Trial
Principal Investigator: Sujata Ghate
Study looking for predictive value of breast MRI. Study will follow subjects for 2 years. How long will study last? It was also mentioned that CRU would benefit from having a representative. The Radiology CRU committee voted to send the study back to the study team with questions. The questions have mainly to do with feasibility of recruitment.
- Pro00072427 Expanded access protocol for therapeutic use of 177Lu-DOTA0-Tyr3-Octreotate in patients with inoperable, somatostatin receptor positive, midgut carcinoid tumors, progressive under somatostatin analogue therapy.
Principal Investigator: Salvador Borges-Neto
Study not discussed.

IV. Federal/Foundation Studies

V. Seed Fund Requests

- Dr. Alexie Riofrio
Study looking for funding to pay for scans done in CAMRD. It was decided to look further into the budget and what the fees in CAMRD are so far.
- Dr. Steve Zhang Asking for increase in funding
Dr. Zhang requested more funds. When this discussed in the meeting it was believed that the study had already gotten the maximum amount. It was suggested that he look for funding from other sources. After the meeting, it was discovered that the maximum amount was not awarded earlier so there was \$886 available to award.

VI. Quick updates

- Regulatory and Protocol Review Position
Antonina Poole starting May 1st
Steve Shipes briefly mentioned that Antonina will starting and little about her background.
- Putman Vision Award 2016
A score card will be sent to everyone to vote on the three submissions.

VII. **Old Business**

- Research Marketplace, review of seed grants are pending

VIII. **New Business**

- Establishing a “Research Work Group”
 - Hopes of creating a platform to better establish relationships and to provide opportunities for the teams to talk through research studies, answer/ask questions, etc.
 - Establish a process whereby any “fails” generate a review of that particular study. In doing so, trends can be established and remediation strategies can be employed. Philosophically, these would include similar multidisciplinary resources as the work group list above. Would also include ad.hoc members depending on where the “fail” occurred. This would be very similar to that which exists on the clinical side (Root Cause Analysis) when a failure occurred in the delivery of care.